

# EXHIBIT 76

aCEP buyers' guide: forced air warming devices

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Initial stakeholder consultation – August 2008

Dear stakeholder

Thank you for agreeing to be involved this project. We aim to produce a buyers' guide for forced air warming devices for use by NHS purchasers. These devices are recommended by NICE. We have done some preliminary research on the issues surrounding forced air warming devices. However we would like you to direct our subsequent research activity. Please answer the following 10 questions. Most of these are open ended – feel free to write as much or as little as you wish.

**This is preliminary research to inform the project plan, so please reply as soon as possible.**

Please complete electronically and return this form by email to:

[andrew.cleves@cardiffandvale.wales.nhs.uk](mailto:andrew.cleves@cardiffandvale.wales.nhs.uk)

Field Code Changed

If you prefer to discuss the questions by telephone please call Andrew Cleves on:

029 20 68 21 25

*Many thanks for your help.*

Questions                    Kevin Robinson, Arizant UK

*NB: Conducted by telephone – typed up by Andy  
Additional revisions by Arizant Healthcare 8-22-08*

1. Which forced air warming devices do you have experience of? Please list:

All Arizant Products e.g. Bair Hugger & Bair Paws (patient controlled device for ward areas)  
Bair Paws has a smaller blower unit, and does not have the same filtration standard as Bair Hugger so is not suitable for use in theatre.

Recommends I look at:  
200977D  
597C  
200742F  
595E

NB the model 500 is considered obsolete and is scheduled for withdrawal (time for supplying spare parts has expired) – see addendum document.

2. How many devices do you use (or supply) per year? Please describe in terms of 'one-off' purchase e.g. FAW control unit and also consumables/disposables:

We are the market leader in the UK, holding about XX% of the market. [Julian, do we need to say this? What is the correct figure? We have 83-85% of FAW market share in UK. We don't have to mention it.]

Hospitals buy the blankets, Arizant loans the blowers; although a minority of hospitals have bought Bair Hugger blowers.

Most hospitals tend to buy through an intermediary e.g. NHS supply chain, Universal Hospital Supplies (Southern Syringe Services) etc. or else organise into 'buying hubs'.

Therefore nobody buys at the list price.

Servicing – some hospitals service the blowers they use. Arizant now only have a small number of engineers in house but offer servicing for a fee through GAS service.

3. Where are the devices used? Please describe in terms of patient pathway (e.g. pre, peri & post-operatively) and clinical setting (e.g. according type/length of surgery or according to patient characteristics):

The blankets are used for people of all ages – neonatal to elderly patients. Bair Hugger blankets have application throughout the care setting. Today, Bair Hugger can be found in the pre-op, operating theatre, recovery, specialty procedure suites such as the cardiac cath lab, interventional radiology, heart rooms, emergency rooms, and inpatient and outpatient settings. 23 styles of Bair Hugger blankets available in the UK.

4. Are forced air warming devices easy to use?

Yes – easy to apply and use. Arizant offers field training to support this.

5. Are there any problems associated with using forced warm air devices?

See attached sheet for contraindications.

6. What makes a forced air warming device a good forced air warming device?

The Bair Hugger is a system comprised of a warming unit and an attached blanket.

Important attributes of a warming system are:

1. Air-Flow speed – cubic feet per minute (determines the time the air spends inside the blanket and how much thermal energy from the air reaches the skin surface of the patient) The velocity and volume of air delivered to the blanket are both important
2. Temperature sensing at the hose end to account for temperature gradient along the hose.
3. Air filters (0.2 micron filter or better).
4. Internal clock to keep track of hours in use.
5. Warming unit safety features
  - a. Maximum temperature setting should not exceed 43C.
  - b. Proper temperature sensors to ensure rapid shutdown should the warming unit overheat. These sensors should be multiply redundant.
  - c. Audible and visual over-temperature alarms.
  - d. The ability to test these safety systems without disassembling the warming unit.
6. Blanket – even distribution of air and temperature. This is achieved on Bair Hugger by a manifold and a series of conduits inside the blanket for even distribution – also has the advantage that compressing part of the blanket does not restrict airflow elsewhere.
7. The warming unit should not interfere with the theatre lighting.

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7. What do you feel are the most important factors for us to assess when looking at the clinical effectiveness of forced air warming devices?

1. A strong track record of performance and safety
2. Blower
  - a. Hose-end temperature
  - b. Airflow delivered to the patient
  - c. Effective air filtration
  - d. Selectable temperatures
  - e. Appropriate safety systems (discussed above)
3. Blankets
  - a. A blanket design which evenly distributes the warm air through the blanket (no hot spots).
  - b. Availability of under body blankets, which are suitable for both everyday procedures and those difficult procedures that require full patient access with difficult exposure.
  - c. A broad product offering to ensure the ability to warm virtually all of a care provider's patients.
4. Clinical evidence via outcomes studies published in peer-reviewed journals. (see references below)

[Provide reference list here. Include infection-control papers by Huang, Teenier, Zink, and Barie. Include performance-related RCTs or review articles by XXX. Agreed] I would also include Thiele.

8. What do you feel are the most important factors for us to assess when looking at the cost-effectiveness of forced air warming devices?

1. Performance of the product – how well does it warm the patient?
2. Is the product line flexible enough to warm virtually all of your patients?
3. Extent of company support e.g. customer service, training, education, expertise in the area of temperature management.
4. No requirement to purchase warming unit.
5. Appropriate safety systems.

9. How should we compare different types of forced air warming device? Please rank the three options shown in order of importance (1=most important; 3=least important). Where possible please add a suggestion for how we should achieve the task.

Option	Importance (1-3)	Your suggestion
Conduct a 'user survey' - of anaesthetics teams who operate the devices	2	Clinicians place high value on direct experience and referrals from other clinicians.
Conduct a 'market review' based on published research papers and manufacturers' data	1	There should be a body of high quality, published evidence to support the use of the product.
Conduct a physical test of the device to measure an important parameter which will differentiate between more effective devices and less effective devices	3	Not necessary. It is difficult to perform such tests validly; tests have already been published. [Note: we have reversed the priorities suggested by Kevin. Should we give them a heads-up verbally about this? Probably not necessary as this is Andrew's own interpretation drawn from his telephone conversation with Kevin.]

**Comment [g1]:** We don't want them trying to do their own testing. It's hard to do well and the outcome could be unpredictable. GH

10. Please add below any further comments on how we should evaluate forced air warming devices for the CEP buyers' guide:

Arizant manufactures the *Bair Paws* gown, a convective warming garment that provides warming before, during, and after surgery. Published research shows that prewarming patients prior to surgery is the best way to avoid hypothermia due to *redistribution temperature drop* (a side-effect of *anaesthetic drugs*). The *Bair Paws* gown is a comfortable, convenient, and cost-effective way to do this.

